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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/764,681      | 01/18/2001  | Markus Haller        | P-9418              | 6923             |

27581 7590 08/02/2004

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EXAMINER


PRIETO, BEATRIZ

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

2142

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |   |  |
|------------------------------|-------------------------------|---|--|
| <b>Office Action Summary</b> | Application No.<br>09/764,681 | Applicant(s)<br>HALLER ET AL.  |  |
|                              | Examiner<br>Prieto B          | Art Unit<br>2142  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2001.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/01 &amp; 1/03</u> | 6) <input type="checkbox"/> Other: _____  |



### ***DETAILED ACTION***

1. This communication is in response to Application No. 09/764,681 filed 01/18/01, claims 1-59 has been examined.

### ***Claim Objection***

2. Claims 1 and 29 recite the clause, "communication system" in line 20 of claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 56 recites the clause, "the system" on line 25, and further on the same line, recitation of "the module", there is also insufficient antecedent basis for this limitation.

### ***Claim Rejection under 35 U.S.C. 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this case, it is not clear whether the claim is a method claim (i.e. software updating communication module) or a system claim, where components of a system following the intended user are recited. Further, being a "software updating communication module" and a "communication module" recited (i.e. on lines 25 and 27, respectively), subsequent recitation, "the module" raises the uncertainty as to which module reference is made to. For the purposes of examination the claim will be treated as a method claim and the module refers to the communication module.

### ***Claim Rejection under 35 U.S.C. 101***

5. Claims 56 and 58-59 are rejected under 35 U.S.C. § 101, which reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 56 and 58-59 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. In this case, computer-related inventions whether

descriptive or functionally descriptive material are non-statutory categories when claimed as descriptive material *per se* (see *Warmerdam*, 33 F.3d at 1360 USPQ2d at 1759), falling under the "process" category (i.e. inventions at that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) ("The term process means, art, or method, and includes a new of a known process, machine, manufacture, composition of matter or material"). Functional descriptive material: "data structures" representing descriptive material *per se* or computer program representing computer listing *per se* when embodied in a computer-readable media are still not statutory because they are not capable of causing functional change in the computer. However, claimed computer-readable medium encoded with a data structure defined structural and functional interrelationships between the data structure and the computer software and hardware component, which permit the data structure's functionality to be realized, and is thus statutory (see MPEP 2106).

*Claim Rejection under 35 U.S.C. 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejection set forth in this office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in the section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 5, 7, 8, 10-22, 24-26, 28-30, 32-35, 37-49, 51-53, and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,456,692 Smith, Jr. et. al. (Smith hereafter) in view of U.S. Patent No. 5,720,770 Nappholz et. al. (Nappholz hereafter).

Regarding claim 1, Smith teaches substantial features of the invention as claimed, including a system (Figs.1 and 5-6) for monitoring the performance of pacemaker (20 of Fig. 1) (IMD) implanted within a body of a patient (col 6/lines 35-39 and col 10/line 35-47), or monitoring the health of the patient (col 9/lines 54-58 and col 7/lines 3-23), the system comprising:

the IMD (20) being capable of bi-directional communication link (44) with a external programmer (46) ("communication module") located external to the patient's body (see Figs. 1 and 6);

the IMD (20) comprising a memory (40) having software loaded therein (Figs. 5-6) and for loading software from the communication module (46) (col 20/lines 27-30);

means for permitting the software to be updated (steps on Figs. 3-4) (col 5/lines 23-44, col 9/lines 6-24) after the IMD has been implanted within the patient's body (col 4/lines 5-22, 28-37, 50-60);

the communication module (46) comprising means for updating software loaded in the IMD (Figs. 3-4, col 5/lines 21-34, col 4/lines 5-13 or col 11/lines 51-54);

a remote computer system (64 of Fig. 6) capable of initiating the downloading of updated or new software to the IMD (20) via the communication module (46) (col 14/lines 44-51, update software steps of Figs. 3-4 or new software steps of Fig. 11 and col 20/lines 50-53); however Smith is silent regarding the use of a mobile telephone;

Nappholz teaches a system/method for remotely delivering therapy to a patient through an implanted medical device (abstract), the system including an implantable medical device (ICD-12) having a bi-directional communication link (24) with a communication module (14) located external to the patient's body (Fig. 1) (col 3/lines 61-col 4/line 9 and col 5/lines 15-18);

the communication module (14) including a mobile telephone and repeater, capable of receiving and transmitting information via a communication network (26 and 30) (col 4/lines 6-11, 16-20 and col 5/lines 20-25); and

a communication system (26 or 8) capable of bi-directional communication with the mobile phone (14) and a remote computer system (27) (col 4/lines 6-20) and supporting communication between the remote computer system (27) to the IMD (12) through the communication module (14) via said communication system (col 6/lines 64-col 7/line 3, 23-27, 38-44, 50-52, 59-64).

It would be obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for updating and replacing software programs on an implanted medical device from a remote computer system through a communication module and the suggestion of using telephone base communication medium, associated procedures and protocols for establishing said communication, the teachings of Nappholz having the same intended purpose would be readily apparent. Given the teaches of Nappholz for providing communication in any combination between the implanted device, the patient, the physician or health care provider facility and personnel using an external module comprising multiple components each providing their intrinsic functions, yet configured to communicate with each other, one ordinary skilled would motivation to apply the teachings of the Nappholz because in doing so the patient is provided with full mobility, and further both the patient and the device can communicate with a remote physician, hospital or care facility using commercially available communication technology.

Regarding claim 2, wherein the communication module incorporates the mobile telephone (Nappholz: 14 of Fig. 1, see col 5/lines 20-25).

9. Claims 3-4 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Nappholz in further view of U.S. Patent No. 5,497,339 Bernard.

Regarding claims 3-4, however the Smith nor Nappholz references teach the integration of a personal mobile telephone with a personal digital assistant or their separation into separate devices.

Bernard teaches the multiple integration of functional capabilities to a PDA, teaching a PDA with cellular phone capabilities (col 1/lines 39-57, col 3/line 49-col 4/line 16) and include switching communication function for switching data between cellular and telephone communication links and necessary supporting data conversions/circuitry rx-tx functions (col 16/lines 38-65) associated including the capability to remotely download software to the integrated unit (Fig. 9A).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the Smith suggestions of using a Personal Communication Network (PCN) for interrogating the implanted device to assess its operation or the patient's health through the communication module (14). One ordinary skilled would be motivated to utilize Bernard teachings for combining telephone and personal communication devices, such as PDA functionalities because in doing so the patient can further schedule his/her intake medications and/or appointments. The advantages of integration/separations of component functionalities are readily apparent to one ordinary skilled in the art, for example, separation of function in components enables the device to continue to operate will other components are being either replace/updated as taught by one of the applied reference, further separating components functions into separate devices, will enable a patient cost conscientious if desirable the option to select/purchase the device based on the desired functions need and his/her means.

Regarding claim 5, wherein the IMD and the communication module communicate with one another using radio-frequency telemetry (Nappholz: col 4/lines 6-9, and col 5/lines 15-19).

Regarding claim 6, wherein the communication module further comprises a microprocessor (Nappholz: 90 of Fig. 3), and one RF communications circuit for transmitting information to and receiving information from the IMD (Nappholz: 124 and 74/76 of Fig. 3).

Regarding claim 7, data output port, cable and connector for connection to a mobile telephone data input port of the mobile telephone (Nappholz: 62 of Figs. 3, 4 and 4B col 5/lines 25-34).

Regarding claim 8, a memory thereof computer readable software for initiating and maintaining communications with the mobile telephone using standardized handshake protocols (Nappholz: col 8/lines 19-25).

10. Claims 9 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Nappholz in further view of U.S. Patent No. 5,342,408 deCoriolis et. al. (deCoriolis hereafter).

Regarding claim 9, however the above-mentioned prior is silent regarding telemetry signal strength indicator;

DeCoriolis teaches a telemetry system/method including a signal strength indicating means for providing an indication of received signal strength at an external mode (abstract).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for monitoring the parameter associated with the operation of the implanted device, as well as the patient health, the teachings of deCoriolis for the same objective would be readily apparent. One would be motivated to monitor the operation of the implanted device for assuring accuracy of the transmitted data provided by the implanted device, the external device's telemetry receiving circuitry must receive the maximum signal strength possible, thereby the need for an indication of the signal strength so that the reception circuitry may be properly programmed.

Regarding claim 10, wherein the communication module further comprises a memory for storing software downloaded to the IMD (Smith: col 12/lines 37-39).

Regarding claim 11, wherein the communication module comprises a battery (50A) or an I/O interface (44) supporting 20, 30, and 32 communication links (Nappholz: Fig.1).

Regarding claim 12, wherein the communication module is adapted to receive electrical power from a portable energy source (50A) disposed to there within (Nappholz: Fig. 1)..



Regarding claim 13, however the above-mentioned prior art does not explicitly teach wherein the communication module is plug-and-play compatible with the mobile telephone.

Official Notice (see MPEP § 2144.03 Reliance on "Well Known" Prior Art) is taken that plug-and-play was old and well known in the Data Processing art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include a plug-and-play application compatible with the mobile telephone because give motivation use add-in cards that are easy to install and use and take advantage of their extremely high memory capacities optimal for many mobile and portable applications (e.g. mobile telephones), such PC cards have become widely used for mass data storage applications, and are a popular alternative for conventional add-on card implemented non-volatile memory solutions such as rotating hard disks and battery-backed SRAM, especially for personal data assistants (PDAs).

Regarding claim 14, wherein the communication module (14), upon receiving instruction from the remote computer system or a remote health care provider (27), upload data therefrom (Nappholz; col 2/lines 41-45, col 2/lines 65-col 3/line 3, col 4/lines 11-20) or including means for interrogating the IMD from a remote computer system through the communication module (Nappholz; 13/lines 44-col 14/line 36).

Regarding claim 15, the wherein communication module (14) comprises means for storing information obtained from the IMD (12) in a memory (49 or 31) (Nappholz: col 7/lines 8-13 and col 8/lines 15-18, or memory (31) see col 8/lines 19-28).

Regarding claim 16, wherein the communication module (14) further comprises means for relaying information obtained from the IMD (12) to the remote computer (27) via the mobile telephone (14) over computer systems (26 or 8) (Nappholz: col 6/line 64-col 7/line 64).

Regarding claims 17-19, these claims are substantially the same as system claims 14-16, discussed above, same rationale of rejection is applicable.

Regarding claim 20, wherein the communication system (26 or 8) comprises a mobile, wireless or cellular based telephone network (Nappholz: col 4/lines 9-11 or col 7/lines 23-27).

Regarding claim 21, wherein the communication module (14) comprises means (106 of Fig. 3) for managing (storing and delivering) update software relating to the operational or functional parameters of the IMD (Nappholz; col 6/line 64-col 7/line 3, 50-64 and col 5/lines 57-60).

Regarding claim 22, wherein the communication module further comprises means for detecting an abnormal condition ("fault") in the operation or circuitry thereof (Nappholz: col 1/lines 23-31).

11. Claims 23 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Nappholz in further view of U.S. Patent No. 3,972,320 Kalman.

Regarding claim 23, however the above-mentioned prior art is silent with respect to correcting a detected fault in operation or circuitry of the communication module and means for notifying the remote computer system or the patient that the fault has been corrected.

Kalman teaches a system/method related medical devices (col 1/lines 5-11), including a device having means (10 of Fig. 1) for detecting a fault in operation or circuitry of itself and means (10 of Fig. 1) for notifying a remote computer system a fault needs to be corrected (col 5/lines 29-66 and col 25/lines 15-61).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for monitoring the performance of an IMD and the patient hosting said device through a communication device which acquires both patient and device status information for further transmission the remote physician and/health care providers locations, to assure that this intermediate device serving as point of relay with the external world is provide with fault tolerant measure. Thereby, the self-testing and notification mechanism taught the Kalman would be readily apparent. One would be motivated to enhance Smith systems with the teachings set for in Kalman reducing communication to a specific location only under predetermined condition is detected and generate specific alarm notification based on the detect fault being patient or device malfunction related and further notify for example a billing related remote computer that new or updated software has been downloaded to the implanted device for correcting detect fault for further account for software distribution services

Regarding claim 24, wherein the communication module comprises means for detecting a fault in the operation or circuitry of the IMD (Nappholz: col 1/lines 23-31).

Regarding claim 25, including limitations discussed on claim 23 and further wherein the communication module comprises means for correcting a detected fault in the operation or circuitry of the IMD (Nappholz: col 1/lines 23-31).

Regarding claim 26, means for obtaining ("mining") patient history or performance parameter integrity or software status from the communication module (Nappholz: col 7/lines 1-19).

12. Claims 27 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Nappholz in further view of U.S. Patent No. 5,258,906 KROLL et. al. (Kroll).

Regarding claim 27, however the Smith and the Nappholz references are silent regarding the generation of invoices in their systems;

Kroll teaches a system/method related to medical device systems, including the generation of invoices in such systems. Kroll teaches a communication device (12 of Fig. 1) comprising an invoice generating entity communicatively coupled to a medical device (21 of Fig. 1) (col 3/lins 21-49), the invoice generating device configured to generate an invoice (col 3/line 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Smith for monitoring an implanted medical device in a patient, and communicating with physicians and health care personal, the teachings of Kroll for providing an invoice generation mechanism related to these services would be readily apparent. One skilled in the art would be motivated given the transmission mechanism, self-contained modularity and add-on capability of the Smith-Nappholz system to further include the generation and transmission of formatted invoices for processing and delivering for the remuneration of rendered services based on actual metered usage of the device systems including for example the implanted device and the mobile telephone.

Regarding claim 28, the communication module comprises means for monitoring the performance of the IMD or for monitoring physiologic signals or data indicative of the patient's health status (Nappholz: col 1/lines 23-31).

Regarding claim 29, this system claim is substantially the same as claim 1 combined with claim 2 or 3, same rationale of rejection is applicable.

Regarding claim 30, this is in substance the same as claim 2, discussed above, same rationale of rejection is applicable.

Regarding claim 31, this is in substance the same as claim 3, discussed above, same rationale of rejection is applicable.

Regarding the system claims 32-49, 51-53 and 55 are substantially the same as the system claims 5-22, 24-26 and 28, respectively, wherein the communication module in the latter further comprises either the features of claim 2 or 3, same rationale of rejection is applicable.

Regarding claim 56, this software ("software updating communication module") claim comprises the elements of the system claim 1, discussed above, same rationale of rejection is applicable.

Regarding claim 57, this apparatus claim (either a telephone or PDA), essentially, combined claim 1 and claim (2 or 3), discussed above, comprises the system elements discussed on claim 1, thereby, same rationale of rejection is applicable.

Regarding claim 58, this method claim comprising the same elements of the system claim discussed above, including downloading software to the IMD from a remote computer through the communication module comprising a telephone, same rationale of rejection is applicable. Claim further recites, the method comprising: the remote computer system determining that the software loaded in the memory of the IMD should be updated and or changed (Smith: col 12/lines 1-11).

Regarding claim 59, this method claim comprises substantially the same system element as those discussed on claims 1 and 2/3, and 58, same rationale of rejection is applicable.

### ***Double Patenting Rejection***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claim 1-2, 29, and 56-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 7, 10, 13-14, 16-17, 19, 21, 29, 32, and 34 of U.S. Patent No. 5,752,976 Duffin et. al. (Duffin hereafter) in view of U.S. Patent No. 5,456,692 Smith Jr. et. al. (Smith hereafter).

A question of patentability is raised with respect to representative claims 1-2, 29 and 56-59 of the instant application rejected under the judicially created doctrine of "obviousness-type" double patenting with respect to U.S. Patent No. 5,752,976 in view of Smith U.S. Patent No. 5,456,692.

Regarding claims 1-2, 29 and 56-59, Smith teaches substantial features of the invention as claimed, including a system (Figs. 1 and 5-6) for monitoring the performance of pacemaker (20 of Fig. 1) (IMD) implanted within a body of a patient (col 6/lines 35-39 and col 10/line 35-47), or monitoring the health of the patient (col 9/lines 54-58 and col 7/lines 3-23), the system comprising:

the IMD (20) being capable of bi-directional communication link (44) with a external programmer (46) ("communication module") located external to the patient's body (see Figs. 1 and 6);

the IMD (20) comprising a memory (40) having software loaded therein (Figs. 5-6) and for loading software from the communication module (46) (col 20/lines 27-30);

means for permitting the software to be updated (steps on Figs. 3-4) (col 5/lines 23-44, col 9/lines 6-24) after the IMD has been implanted within the patient's body (col 4/lines 5-22, 28-37, 50-60);

the communication module (46) comprising means for updating software loaded in the IMD (Figs. 3-4, col 5/lines 21-34, col 4/lines 5-13 or col 11/lines 51-54);

a remote computer system (64 of Fig. 6) capable of initiating the downloading of updated or new software to the IMD (20) via the communication module (46) (col 14/lines 44-51, update software steps of Figs. 3-4 or new software steps of Fig. 11 and col 20/lines 50-53).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the teachings of Duffin for monitoring a patient's condition, obtaining pertaining condition data from an implanted medical device, providing by the implanted medical device therapy (therapeutical treating) to the patient and provide reprogramming commands to said implanted device having stored therein programmed operating commands for controlling operations of the implanted device from an external patient communication control device ("communication module") to further apply Smith's teachings for updating and reprogramming said implanted device by downloading software into it through the external patient communication control device and/or through a remote computer system. One ordinary skilled would be motivated to update or replace current programming with new software providing the patient with new features or functions, or perhaps customize its features to the patient's need without explanting the device from the patient, making the enhancement or upgrade less expensive, further reducing the health risk associated with the explant/implant procedure of the prior art.

*Pertinent Prior Art:*

15. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure; pertinence is presented in accordance with MPEP§ 707.05.

U.S. Patent No. 5,526,411 (June-1996)

Krieter teaches a personal device comprising an integrated portable, cellular phone and personal digital assistant (PDA), wherein additional functionality may be included within body structure device, or may be added by circuitry in an expansion slot.

U.S. Patent No. 4,979,507 (Dec. 1990)

Heinz et. al. teach an external programming device for monitoring the performance of an implanted medical device within a body of a patient, including an external programming device including a telemetry signal strength indicator.

U.S. Patent No. 4,055,189 (Oct. 1977)

Auerbach et. al. discloses as prior art, conventional systems which monitor implanted medical devices, such a pacer by means of an external equipment sensing the various operations of the pacer functions. Auerbach et. al. suggest a completely self-contained unit within the implanted pacer which will contain all of the monitoring and storage equipment necessary to both detect a pacer malfunction of the various types, and in addition, to take corrective action in instances where such failures, as are described above, have occurred.

U.S. Patent No. 5,720,771 (Feb. 1998)

Snell teaches a communication system for monitoring the performance of an implantable medical device, implanted within a patients body, the device capable of communicating bi-directionally with an external communication device, the communication device further configured to communicate with a remote computer device over a telephone communication medium relaying information obtained from the implanted device.

Ref D: U.S. Patent 5,815,426;

Jigour et. al. teaches a variety of add-on cards and modules for use in digital systems such PCs have enjoyed a measure of success in various memory-intensive applications, some of these memory add-on cards use flash memory, and are known as flash PC cards have become widely used for mass data storage applications, especially for personal data assistants (PDAs). Flash PC cards are more rugged and space efficient, are silent, consume less power, provide higher performance (in most cases), and provide a removable form-factor. As an alternative to battery-backed SRAM PC cards, flash PC cards typically offer higher-densities and lower cost per bit and are not as limited by reliability and temperature issues associated with batteries used in the battery-backed SRAM PC cards. PC cards that support the ATA interface use an on-card ATA controller, which allows "plug-and-play" compatibility between portable computers and PDAs. PC cards can be made available at extremely high memory capacities because of improved memory technology; however, such extremely high memory capacities are in excess of what is optimal for many mobile and portable applications. Moreover, although the insertion lifetime of 68-pin PC card connectors, which is about 10,000 cycles, is generally adequate for portable computers and PDAs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prieto, B. whose telephone number is (703) 305-0750. The Examiner can normally be reached on Monday-Friday from 6:00 to 3:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Jack B. Harvey can be reached on (703) 305-9705. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3800/4700.

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Patent Examiner